

Notice of Allowability

Application No.

10/507,421

Examiner

Iqbal H. Chowdhury, Ph.D.

Applicant(s)

NARIMATSU ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/18/2006.
2. ☒ The allowed claim(s) is/are 1,2,6,7 and 20-22.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>01/11/07</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Application Status

In response to a previous Office action, a non-final requirement (mailed on May 18, 2006), Applicants filed an amendment on October 18, 2006, amending claims 1-2, 5 and 7.

Claims 1-2, 5-16 and 20-26 are currently pending in the instant application. Claims 1, 2, 5-7 are now under consideration. Claims 8-16, 20-26 remain withdrawn as they are drawn to non-elected invention.

Applicants' arguments filed on October 18, 2006, have been fully considered and are not deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Election/Restriction

Claims 1-2 and 6-7 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 20-22, are directed to the process of using the allowable product, previously withdrawn from consideration as a result of a restriction requirement, mailed on 11/21/2005 are hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 8-16 and 23-26 are directed to the invention(s) of Groups II and Group III (in part, claims 23-26) require all the limitations of an allowable product claim, and have NOT been rejoined.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, **the restriction requirement of groups I and III (in part, claims 20-22) as set forth in the Office action mailed on 11/21/2005 is hereby withdrawn.** In view of

the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Thomas Siepmann, the representative of the instant application on January 12, 2007.

Amend claims as follows:

Claim 6, line 1, after "claim" delete "5" and replace with "2".

Claim 7, line 1, after "comprising" delete "a region having".

Claim 20, line 2, after "claim 6" delete "or determining the expression amount of the gene coding for said protein".

Claims 5, 8-16 and 23-26 are cancelled.

Allowable Subject Matter

Claims 1-2, 6-7 and 20-22 are allowed.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: The applicant has claimed an isolated protein having an amino acid sequence shown in SEQ ID NO: 1, or an amino acid sequence having a homology of not less than 95% to the amino acid of SEQ ID NO: 1, which has an activity to transfer N-acetylglucosamine to a non-reducing terminal of Gal β 1-4Glc or Gal β 1-4GlcNAc group through β 1,3-linkage and method of use of said protein for diagnosis of cancer. In view of Applicants' claim amendments, all prior rejections are withdrawn. The Examiner has rejoined claim 6 and claims 20-22, drawn to method of use of said allowed polypeptide for diagnosis. The prior art does not teach an isolated protein having an amino acid sequence shown in SEQ ID NO: 1 or SEQ ID NO: 3 or an amino acid sequence having a homology of not less than 95% to the amino acid of SEQ ID NO: 1, which has an activity to transfer N-acetylglucosamine to a non-reducing terminal of Gal β 1-4Glc or Gal β 1-4GlcNAc group through β 1,3-linkage as claimed. A standard search did not produce any prior art that suggests or teaches the claimed invention. The claimed invention is novel and nonobvious over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury, Ph.D. whose telephone number is (571) 272-8137. The examiner can normally be reached on Monday-Friday from 9:00-5:00.

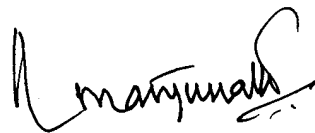
Art Unit: 1652

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Iqbal Chowdhury, PhD, Patent Examiner
Art Unit 1652 (Recombinant Enzymes)
US Patent and Trademark Office
Rm. REM 2B69, Mail Box. 2C70
Ph. (571)-272-8137, Fax. (571)-273-8137

IC



MANJUNATH N. RAO, PH.D.
PRIMARY EXAMINER